

Policy Oversight Committee Meeting Summary
Conference Call
February 7, 2014 3-4 pm EST
Yolanda Becker, MD Chair

Introduction

The Policy Oversight Committee met via *Citrix GoTo* on 2/7/2014 from 3:00 – 4:00 pm EST to discuss OPTN/UNOS Committee public comment proposals for spring 2014 and make recommendations to the Executive Committee about whether these proposals should go to public comment.

The following is a summary of the Committee's discussions.

POC Review of Spring 2014 Public Comment Proposals

Preparation for this meeting involved compiling the public comment proposals and creating a survey with instructions to rate each proposal according to 6 factors:

1. How well it aligns with the OPTN strategic plan and goals
2. Significance of the problem and evidence
3. Proposed solution
4. Target population impact
5. Plan for collaboration
6. Cost/benefit

The survey also included the general question "Proceed to public comment?" which could be answered yes or no.

The POC research liaison compiled the results of the survey and the committee liaison prepared a consent agenda and a discussion agenda. The consent agenda included proposals that had all "yes" answers to the "Proceed to public comment?" question. The discussion agenda included proposals that had even a single "no" answer.

Summary of discussion

- Role was taken to ensure a quorum.
- Committee Chair, Dr. Yolanda Becker, gave a brief overview of the process and goals for the public comment proposal review.
- The Committee briefly discussed the items on the consent agenda and then voted to make a recommendation to the Executive Committee that all these proposals go to public comment. Proposals that were on the consent agenda include:
 1. Proposed ABO Subtyping Consistency Policy Modifications - Operations and Safety
 2. Proposed ABO Blood Type Determination, Reporting, & Verification Policy Modifications - Operations and Safety
 3. Proposal to Align OPTN Data Policies with the 2013 PHS Guideline for Reducing Transmission of HIV, HBV, and HCV Through Solid Organ Transplantation – DTAC
 4. Proposal to Cap the HCC Exception Score at 34 - Liver Committee
 5. Proposal to Delay HCC Exception Score Assignment - Liver Committee
 6. Proposed Membership and Personnel Requirements for Intestine Transplant Programs - Liver Committee & MPSC

7. Proposal to Modify Existing or Establish New Requirements for the Psychosocial & Medical Evaluation of all Living Donors - LD Committee
8. Proposal to Notify Patients Having an Extended Inactive Status - TX Coords Committee
9. Proposal to Allow Non-substantive Changes to the OPTN Policies & Bylaws – POC
10. Proposal to Clarify Data Submission & Documentation Requirements – MPSC
11. Proposal to Continue the Adolescent Classification Exception for Pediatric Lung Candidates - Thoracic Committee

The Committee voted unanimously (*16 yes, 0 no, 0 abstentions*) to make the recommendation to the Executive Committee that these proposals go out for spring 2014 public comment.

- Because POC members had questions or concerns, the following proposals were not included on the consent agenda and were reviewed more closely by the Committee:
 1. Expanding Candidate & Deceased Donor HLA Typing Requirements to Provide Greater Consistency Across Organ Types - Histocompatibility Committee
 2. Proposal to Collect ECMO Data Upon Waitlist Removal for Lung Candidates - Thoracic Committee
 3. Proposal to Allow a MPSC Recommendation to the BoD for Approval Consideration of a Non Qualifying TX Program Applicant Located in a Prescribed Geographically Isolated Area - MPSC
 4. Proposal to Require the Collection of Serum Lipase for Pancreas Donors - Pancreas Committee
 5. KPD Histocompatibility Testing Policies - Kidney Committee
 6. Proposal to Modify Existing or Establish New Requirements for the Informed Consent of all Living Donors – Living Donor Committee
 7. Proposal to Require the Reporting of Aborted Living Donor Organ Recovery Procedures – Living Donor Committee

After further discussion, ultimately all of these proposals were approved for public comment. However, the POC made some additional comments and recommendations for these proposals:

- *Proposal to Collect ECMO Data upon Waitlist Removal for Lung Candidates (Thoracic Committee)*- Need to update the proposal to make it clear that this is not a policy language change but only a change to a data collection form in *Tiedi*.
- *Proposal to Require the Collection of Serum Lipase for Pancreas Donors (Pancreas Committee)*- Members of the Committee questioned the cost/benefit of programming this, but believed this proposal should go to public comment for consideration.
- *Proposal to Allow a MPSC Recommendation to the BoD for Approval Consideration of a Non Qualifying TX Program Applicant Located in a Prescribed Geographically Isolated Area (MPSC)* – If this only applies to Puerto Rico, Hawaii, and Alaska why don't we just say that (instead of non-contiguous areas of the US)? If you are going to have special dispensation (relaxed standards) for special situations, then maybe they should have special monitoring?
- *Proposal to Modify Existing or Establish New Requirements for the Informed Consent of all Living Donors (Living Donor Committee)*- There is specific language in the proposal for what might happen if you give up a kidney or part of a liver, but nothing about what happens if you give up a part of a lung, or a part of another organ that we haven't

considered. Might want to have some general language that covers the expected informed consent related to the loss of function associated with donation.

The Committee then voted unanimously (*16 yes, 0 no, 0 abstentions*) to make the recommendation to the Executive Committee that these proposals also go out for spring 2014 public comment, along with the recommendations above.

- The meeting adjourned at 3:56 pm.

Next steps

The Committee's recommendations will be presented to the Executive Committee at a conference call on March 5, 2014.